Stability Testing in Immunohistochemistry

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HSL-Advanced Diagnostics is a large tertiary referral centre. In 2023, the laboratory is expected to perform over 340,000 IHC tests and continues to experience growth rates between 15-20% per year. Due to the high workload and the esoteric nature of testing provided, a high proportion of tests are performed using concentrated primary antibodies. Since 2020, the laboratory has had a dedicated process improvement project to reduce waste while increasing the quality of service. As part of this wider project, the laboratory sought to establish stability data for diluted antibodies and tissue sections. The aim of this project was (1) anticipate workload demand; (2) establish stability data for each test using concentrated antibody; (3) tailor diluted antibody production to optimise demand versus stability; (4) develop a system of continuous monitoring and adjustment of diluted antibodies produced and (5) replicate this study for tissue stability. The aim of this poster is to provide Biomedical Scientists with a framework from which to develop a similar project for their service.

Keywords: Immunohistochemistry, Stability Testing, Primary Antibodies, Tissue Controls

Methods

Antibody & Control Stability Testing

All concentrated primary antibodies and control slides were prepared with sufficient volume for testing at Week 1, Week 2, Week 3, Week 4, Month 2 and Month 3. This considered the possible need for repeat testing.

In a high volume IHC laboratory, many routine antibodies and their controls slides will be in constant use at room temperature for almost the entirety of their period of use, e.g. Oestrogen Receptor, CD20, AE1/AE3, Ki67 etc.

Testing was carried out across a range of automated IHC instruments, including Leica Bond III, Roche Ultra & Dako Autostainer 48.

For both antibody and control stability testing, a “worst-case scenario” was employed to cover expected usage profiles.

The laboratory facility is a temperature-controlled, air-conditioned environment. Temperature monitoring is carried out using the Kelsius CoolCheck™ system.

Concentrated Antibody Stability

All diluted antibodies were stored at room temperature (range 22-26˚C) for the duration of this study. All tissue sections used in the testing of antibody stability were cut fresh.

Tissue Control Stability

All control slides were stored at room temperature (range 22-26˚C) for the duration of this study. All antibodies used in the testing of control material stability were prepared fresh.

Stability Test Assessment

All stained slides were independently double assessed by at least one Biomedical Scientist and one Consultant Pathologist. Result was determined using a binary grading system (Pass/Fail).

Laboratory Test Failure Profile

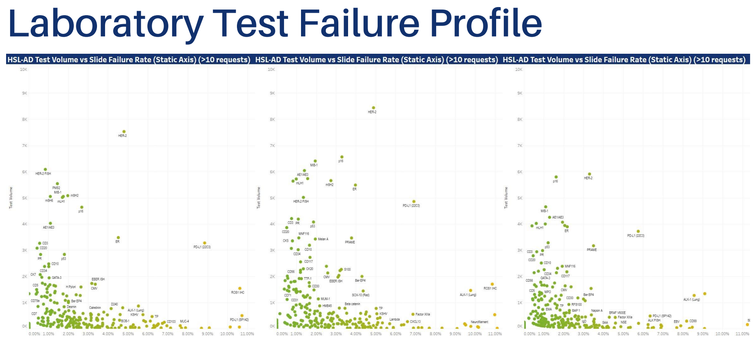

Figure 1. Test Failure 2021, 2022, 2023 (YTD)

Results

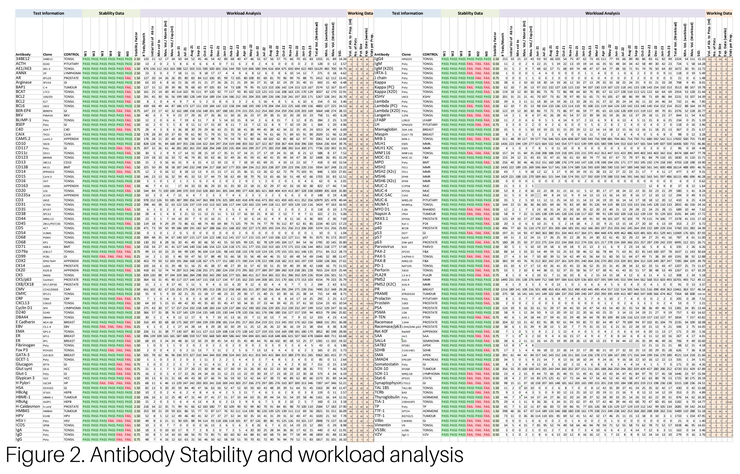

Figure 2. Antibody Stability and workload analysis

Test Information		Stability Data						Working Data	Test Information		Stability Data						Working Data	Test Information		Stability Data						Working Data
Antibody	Control	W1	W2	W3	W4	M2	M3	Control Expiry (Weeks)	Antibody	Control	W1	W2	W3	W4	M2	M3	Control Expiry (Weeks)	Antibody	Control	W1	W2	W3	W4	M2	M3	Control Expiry (Weeks)
34BE12	PROSTATE	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	CK8	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12	MSH6	MMR	PASS	PASS	PASS	PASS	PASS	PASS	12
A1ACT	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	CK8/CK18	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12	MSH6 (Xb)	MMR	PASS	PASS	PASS	PASS	PASS	PASS	12
A1AT	A1AT	PASS	PASS	PASS	PASS	FAIL	FAIL	3	CMV	CMV	PASS	PASS	PASS	PASS	PASS	PASS	12	MUC-1	TUMOUR	PASS	PASS	PASS	PASS	PASS	PASS	12
ABCG2	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	CMVSH	CMV	PASS	FAIL	FAIL	FAIL	FAIL	FAIL	FRESH	MUC-2	MUC	PASS	PASS	PASS	PASS	PASS	PASS	12
ACTH	PITUITARY	PASS	PASS	PASS	PASS	PASS	PASS	12	CMYC	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	MUC-4	MUC	PASS	PASS	PASS	PASS	PASS	PASS	12
AE1/AE3	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	COLIV	PROSTATE	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	MUC-5	MUC	PASS	PASS	PASS	PASS	PASS	PASS	12
AFP1	AFP	PASS	PASS	PASS	PASS	PASS	PASS	12	COX-2	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	MUC-SAC	MUC	PASS	PASS	PASS	PASS	PASS	PASS	12
ALK (D5F3)	ALK LUNG	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	CRP	CRP	PASS	FAIL	FAIL	FAIL	FAIL	FAIL	FRESH	MUC-6	MUC	PASS	PASS	PASS	PASS	PASS	PASS	12
ALK1	ALK LYMPHOMA	PASS	PASS	PASS	FAIL	FAIL	FAIL	1	CXCL13	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	3	MUM-1	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12
ANNX	LYMPHOMA	PASS	PASS	FAIL	FAIL	FAIL	FAIL	2	Cyclin A	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	MYO D1	RHABDO	PASS	PASS	PASS	PASS	PASS	FAIL	6
AR	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	1	Cyclin D1	LYMPHOMA	PASS	PASS	PASS	PASS	PASS	PASS	12	Myogenin	RHABDO	PASS	PASS	PASS	FAIL	FAIL	FAIL	2
ARGN	GI	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	D2AD	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Myoglobin	STRIAD MUSCLE	PASS	PASS	PASS	PASS	PASS	PASS	6
BAP1	TUMOUR	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	DBA44	LYMPHOMA	PASS	PASS	PASS	PASS	PASS	PASS	12	Napsin A	TUMOUR	PASS	PASS	PASS	PASS	PASS	PASS	12
BCAT	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	2	Desmin	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12	Nestin	GI	PASS	PASS	PASS	PASS	PASS	PASS	12
BCL2(100)/DS)	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	1	DOG-1	GI	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	Neurofilament	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12
BCL2 (E17)	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	E Cadherin	BREAST	PASS	PASS	PASS	PASS	FAIL	FAIL	3	Neutrophil elastase	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12
BCL6	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	2	EBER ISH	EBER	PASS	PASS	PASS	PASS	PASS	PASS	12	NKX3.1	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12
BER&P4	GI	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	EBV	EBV	PASS	PASS	PASS	FAIL	FAIL	FAIL	1	NSE	APPENDIX	PASS	PASS	PASS	FAIL	FAIL	FAIL	3
BKV	BKV	PASS	PASS	PASS	PASS	PASS	PASS	2	EMA	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	OCT2	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2
BLIMP	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	ER (6F11)	ER	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	OCT 3/4	SEMINOVA	PASS	PASS	PASS	PASS	PASS	PASS	12
BOB1	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	ER (EP1)	ER	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	p16	p16	PASS	PASS	PASS	PASS	PASS	PASS	12
BRAF V600E	BRAF	PASS	PASS	PASS	PASS	FAIL	FAIL	1	ERG	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	p16 (6H4)	p16	PASS	PASS	PASS	PASS	PASS	PASS	12
BSEP	GI	PASS	PASS	FAIL	FAIL	FAIL	FAIL	3	Factor VIII	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	6	P24	P24	PASS	PASS	PASS	PASS	PASS	PASS	12
C4D	C4D	PASS	PASS	PASS	PASS	PASS	PASS	1	Factor XIIIa	GYNAE	PASS	PASS	PASS	PASS	PASS	PASS	3	p27	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	3
CA125	GYNAE	PASS	PASS	PASS	PASS	PASS	PASS	6	Fascin	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	p40	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12
CA19-9	CA19-9	PASS	PASS	PASS	PASS	PASS	PASS	2	Fibrinogen	GI	PASS	PASS	FAIL	FAIL	FAIL	FAIL	2	p53	GI	PASS	PASS	PASS	PASS	PASS	FAIL	6
CAIX	CAIX	PASS	PASS	PASS	PASS	FAIL	FAIL	12	Fox P3	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	6	p57	p57	PASS	PASS	PASS	PASS	PASS	PASS	12
CALCIT	HORMONE	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	Galectin	ALK LYMPHOMA	PASS	PASS	PASS	PASS	PASS	PASS	3	p63	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12
CALPON	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	2	Gastrin	GASTRIN	PASS	PASS	PASS	PASS	PASS	FAIL	6	Parvovirus	PARVOVIRUS	PASS	PASS	PASS	PASS	PASS	PASS	12
CALRET	TUMOUR	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	GATA-3	BREAST	PASS	PASS	PASS	PASS	PASS	PASS	12	PAX-2	F&K	PASS	PASS	PASS	PASS	PASS	PASS	12
CAM5.2	APPENDIX	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	GCDFP-15	WHOLE BREAST	PASS	PASS	PASS	PASS	PASS	PASS	12	PAX-5	TONSIL	PASS	PASS	PASS	PASS	PASS	FAIL	2
CD10	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	2	GCET-1	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	PAX-8	F&K	PASS	PASS	PASS	PASS	PASS	PASS	12
CD103	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12	GFAP	GFAP	PASS	PASS	PASS	PASS	PASS	PASS	12	PD-1	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12
CD105	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Glucagon	GI	PASS	PASS	PASS	PASS	PASS	PASS	12	PD-L1 (22C3)	PDL1	PASS	PASS	PASS	PASS	PASS	PASS	3
CD117	GI	PASS	PASS	PASS	FAIL	FAIL	FAIL	1	Glut synt	HCC	PASS	PASS	PASS	PASS	PASS	PASS	6	PD-L1 (28-8)	PDL1	PASS	PASS	PASS	PASS	FAIL	FAIL	3
CD15c	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	2	Glut-1	GI	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	PD-L1 (SP142)	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	6
CD123	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	Glypican 3	HCC	PASS	PASS	PASS	PASS	PASS	PASS	6	Perforin	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12
CD13	CD13	PASS	PASS	PASS	PASS	PASS	PASS	2	Granzyme B	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	PGP 9.5	APPENDIX	PASS	PASS	PASS	PASS	PASS	FAIL	6
CD138	BMT	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	H Pylori	HP	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	PLAP	SEMINOVA	PASS	PASS	PASS	PASS	PASS	PASS	12
CD14	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	2	HBcAg	HEPB	PASS	PASS	PASS	PASS	PASS	PASS	12	PLK-1	TONSIL	PASS	PASS	PASS	PASS	PASS	FAIL	3
CD15	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	HBME-1	TUMOUR	PASS	PASS	PASS	PASS	PASS	PASS	12	PMS2	MMR	PASS	PASS	PASS	PASS	PASS	FAIL	6
CD16	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	12	HBsAg	HEPB	PASS	PASS	PASS	PASS	PASS	PASS	12	PMS2 (clone)	MMR	PASS	PASS	PASS	PASS	PASS	PASS	6
CD163	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	2	H-Caldesmon	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12	PPP	TONSIL	PASS	FAIL	FAIL	FAIL	FAIL	FAIL	FRESH
CD19	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	HCG	GYN	PASS	FAIL	FAIL	FAIL	FAIL	FAIL	1	PR	PROSTATE	PASS	PASS	PASS	FAIL	FAIL	FAIL	1
CD1a	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	1	HER-2	BREAST HER-2	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	PRAME	MELAN	PASS	PASS	PASS	PASS	PASS	FAIL	6
CD2	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	HGH	PITUITARY	PASS	PASS	PASS	PASS	PASS	PASS	12	Prolactin	PITUITARY	PASS	PASS	PASS	PASS	PASS	PASS	12
CD20	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	HMB45	TUMOUR	PASS	PASS	PASS	PASS	PASS	PASS	12	Prostein	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12
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CD22	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	12	HSA	GI	PASS	PASS	PASS	PASS	PASS	PASS	12	PSAP	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12
CD23	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	1	HSV I	HSV	PASS	PASS	PASS	PASS	PASS	PASS	12	PSMA	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12
CD235a	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12	ICOS	TONSIL	PASS	PASS	PASS	PASS	PASS	FAIL	6	P-TEN	PTEN	PASS	PASS	PASS	PASS	PASS	PASS	12
CD25	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	12	IgA	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	3	PTH	HORMONE	PASS	PASS	PASS	PASS	PASS	PASS	12
CD27	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	IgD	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Racemase	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12
CD2AP	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	1	IgG	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Racemase/p63	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12
CD3	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	IgG2	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	RCC	RCC	PASS	PASS	PASS	PASS	PASS	PASS	12
CD30	HD	PASS	PASS	PASS	PASS	PASS	PASS	12	IgG4	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Ret 4DF	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12
CD31	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	IgM	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	3	S100	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	3
CD33	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	2	IgM (X20)	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	ROS-1	ROS-1	PASS	PASS	PASS	PASS	PASS	PASS	12
CD34	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Inhibin	GYNAE	PASS	PASS	PASS	PASS	PASS	PASS	12	ROS1-HC	ROS1	PASS	PASS	PASS	PASS	FAIL	FAIL	3
CD35	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Insulin	GI	PASS	PASS	PASS	PASS	PASS	PASS	12	SAA	TuA	PASS	PASS	PASS	PASS	FAIL	FAIL	3
CD38	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	IRTA-1	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	SALL4	SEMINOVA	PASS	PASS	PASS	PASS	FAIL	FAIL	3
CD4	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	12	J chain	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	SATB2	AFOX	PASS	PASS	PASS	PASS	PASS	PASS	12
CD43	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	2	Kappa	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	SDBH	SDBH	PASS	PASS	PASS	PASS	PASS	PASS	12
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CD45	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Kappa (X20)	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	SMA	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12
CD45RA	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Kappa ISH	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	SMA	APOX	PASS	PASS	PASS	PASS	PASS	PASS	12
CD45RO	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	KSHV	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	SMAD4	PANCREAS	PASS	PASS	PASS	PASS	PASS	FAIL	6
CD5	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Lambda	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	SMM	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12
CD54	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	Lambda (PC)	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Somatostatin	GI	PASS	PASS	PASS	FAIL	FAIL	FAIL	3
CD56	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	2	Lambda (X20)	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	SOX-10	TUMOUR	PASS	PASS	PASS	FAIL	FAIL	FAIL	12
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CD61	BMT	PASS	PASS	PASS	PASS	FAIL	FAIL	2	Laminin	PROSTATE	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	SOX-2	SOX2	PASS	PASS	PASS	PASS	FAIL	FAIL	3
CD68 (PGM1)	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	6	Langerin	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	3	Stat-6	STAT6	PASS	PASS	PASS	PASS	FAIL	FAIL	6
CD68 (KP1)	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	LFABP	LFAP	PASS	PASS	PASS	PASS	PASS	FAIL	6	Surfactant	TUMOUR	PASS	PASS	PASS	PASS	FAIL	FAIL	3
CD7	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	12	LH	PITUITARY	PASS	PASS	PASS	PASS	PASS	PASS	12	Synaptophyin	GI	PASS	PASS	PASS	PASS	PASS	PASS	12
CD71	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	1	Lysozyme	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	TAL 1BS	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12
CD79a	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	2	Mamaglobin	BREAST	PASS	PASS	PASS	PASS	PASS	PASS	12	TCRb	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12
CD8	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	Maspin	BREAST	PASS	PASS	PASS	PASS	FAIL	FAIL	2	Tdt	LYMPHOMA	PASS	PASS	PASS	PASS	PASS	PASS	12
CD99	GI	PASS	PASS	FAIL	FAIL	FAIL	FAIL	2	Mast cell tryptase	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12	Thyroglobulin	HORMONE	PASS	PASS	PASS	PASS	PASS	PASS	12
CDX2	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	1	Melan A	TUMOUR	PASS	PASS	PASS	PASS	PASS	PASS	12	TIA-1	TONSIL	PASS	PASS	PASS	PASS	PASS	FAIL	3
CEA	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12	Mesothelin	TUMOUR	PASS	PASS	PASS	PASS	PASS	PASS	12	TP	TP	PASS	PASS	PASS	PASS	PASS	PASS	12
CEAp	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	12	MGMT	TONSIL	PASS	PASS	FAIL	FAIL	FAIL	FAIL	1	TRAP	LYMPHOMA	PASS	PASS	PASS	FAIL	FAIL	FAIL	2
CGa	GI	PASS	PASS	PASS	PASS	FAIL	FAIL	12	MIB-1	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	TTF-1	HORMONE	PASS	PASS	PASS	PASS	PASS	PASS	12
CK14	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	3	MLH1	MMR	PASS	PASS	PASS	PASS	PASS	PASS	12	TTF1 BGTG3/1	TUMOUR	PASS	PASS	PASS	PASS	PASS	PASS	12
CK17	PROSTATE	PASS	PASS	FAIL	FAIL	FAIL	FAIL	12	MLH1 (X2C)	MMR	PASS	PASS	PASS	PASS	PASS	PASS	12	Uroplakin	BLADDER	PASS	PASS	PASS	PASS	PASS	PASS	12
CK18	PROSTATE	PASS	PASS	PASS	PASS	FAIL	FAIL	1	MNF116	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2	Villin	GI	PASS	PASS	PASS	PASS	PASS	PASS	12
CK19	PROSTATE	PASS	PASS	FAIL	FAIL	FAIL	FAIL	6	MOC-31	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	12	Vimentin	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12
CK20	APPENDIX	PASS	PASS	PASS	PASS	PASS	PASS	1	MPO	BMT	PASS	PASS	PASS	PASS	PASS	PASS	12	VS38c	TONSIL	PASS	PASS	PASS	PASS	FAIL	FAIL	3
CK5	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	12	MSA	STRIAD MUSCLE	PASS	PASS	PASS	PASS	PASS	PASS	12	VZV	VZV	PASS	PASS	PASS	PASS	PASS	PASS	12
CK5/p63	PROSTATE	PASS	PASS	PASS	PASS	PASS	PASS	2	MSH2	MMR	PASS	PASS	PASS	PASS	PASS	PASS	12	WT1	F&K	PASS	PASS	PASS	PASS	PASS	PASS	12
CK7	TONSIL	PASS	PASS	PASS	PASS	PASS	PASS	12	MSH2 (X2c)	MMR	PASS	PASS	PASS	PASS	PASS	PASS	12	ZAP 70	TONSIL	PASS	PASS	PASS	FAIL	FAIL	FAIL	2

Figure 3. Tissue Control Stability

Antibody Stability

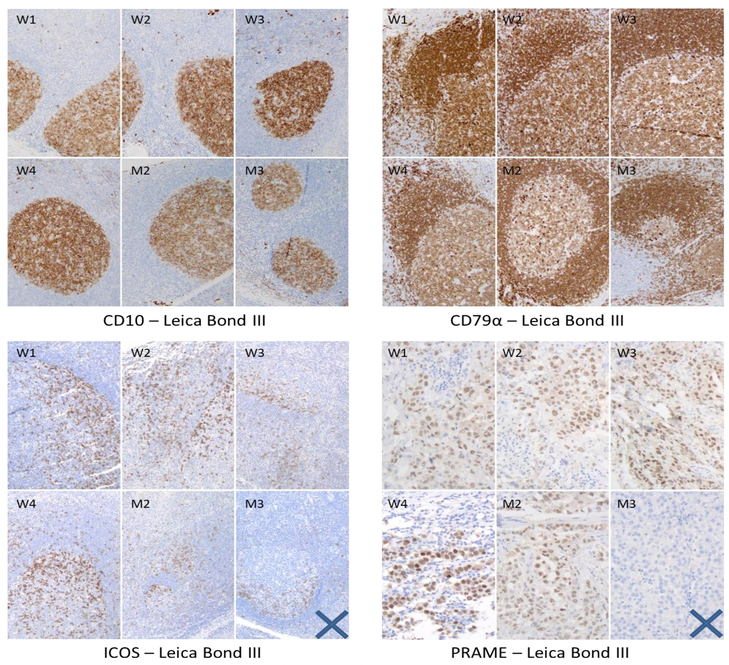

Figure 4. Antibody Stability on Stained Slides

Control Stability

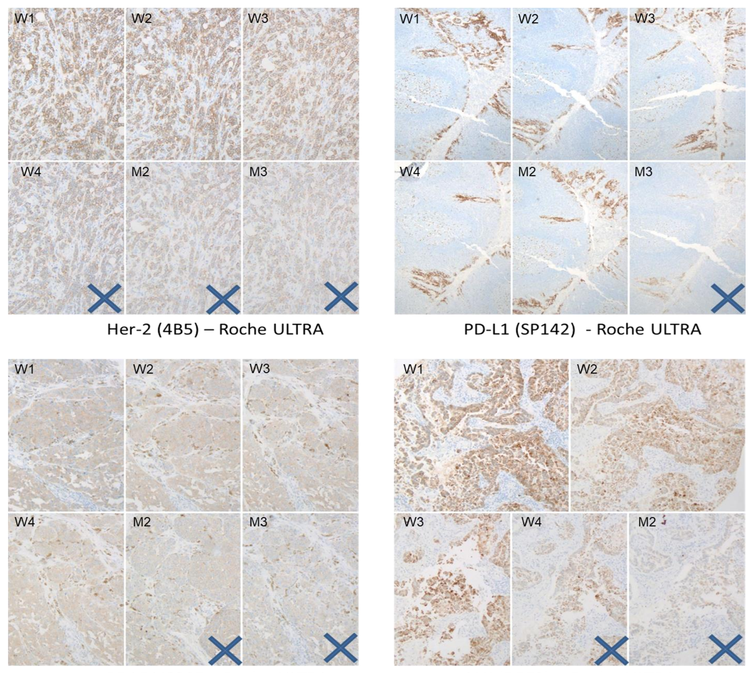

Figure 5. Control Stability on Stained Slides

Discussion & Conclusion

Antibody and tissue stability studies provided our service with much greater insights into how our assays performed in real-time.

The laboratory has been tracking slides failure and its root cause for a number of years (QC data collected on 1 million IHC slides), reducing failure rates while growing our testing service.

Similar studies have been performed by a number of groups regarding the stability of tissue within FFPE blocks or as a tissue section after microtomy, but to our knowledge no group has published any findings of how it directly affected an entire clinical service[1,2].

Likewise, it is standard practice for commercial IHC antibody producers to carry out stability testing of their products, resulting in established expiry dates. However, there is little information of the stability of working antibody dilutions from concentrated antibody products.

Technically, when a laboratory prepares a concentrated antibody into a working dilution, it is manufacturing a new product. While not immediately applicable to clinical laboratories today, CE-IVDR and UKAS/ISO15189:2022 implementation will have a major impact on our services[3]. The results from this work allowed our service to establish expiry dates for antibody dilutions and pre-prepared control sections.

While the results of this poster are not directly translatable into each IHC laboratory, the template used could be adopted by any laboratory to replicate this study into their clinical service, improving the reliability and reproducibility of clinical IHC testing and patient care.

References

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